

REMARKS/ARGUMENTS

Claims 19, 21-26, and 28-34 are pending and were examined. The claims have been amended as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested in view of the following remarks.

Applicants thank Examiner Ryckman for the courteous and helpful interview on February 26, 2009. At that interview, Applicants explained the construction and use of the expansible device described in the present application. In particular, Applicants explained that the device includes a first expansible member that is expanded using a single wire to assume a generally spherical geometry in the lumen of a blood vessel. The first expansible member may be drawn back against the blood vessel wall to occlude a penetration in the blood vessel wall. The device further includes a second expansible member having a cylindrical shape intended to be expanded within the tissue tract leading from the wall penetration to a skin surface.

In view of this discussion, the Examiner suggested that further amendments in the independent claims might serve to better distinguish the cited art. In particular, the Examiner suggested that each claim be amended to recite that the first expansible member be an elongate cylinder having a length sufficient to extend through at least a portion of the tissue tract from the blood vessel to the skin surface, generally as described in paragraph 79 of the present application. Applicants have made such amendments.

Independent claims 19 and 29, the only pending independent claims, as well as various claims dependent thereon were rejected as being obvious over the combination of Latson '003 and Khairkhahan '647. Such rejections are respectfully traversed. Independent claims 19 and 29 are directed at an apparatus and a method of use of such apparatus. The apparatus and method are useful for sealing a puncture site in a body lumen or tissue tract, such as a puncture in a blood vessel at the bottom of a tissue tract. The apparatus includes a first expansible member and a second expansible member. The first expansible member has a spherical shape when it is in the expanded configuration and the second expansible member has a cylindrical shape when in the expanded configuration. Such a configuration is particularly useful for

providing hemostasis in vascular tissue tracts, as illustrated in Figs. 11A-11E of the application and described in paragraphs 76-80.

The Examiner relies on the Latson '003 patent to teach the basic structure of a first expansible member and a second expansible member but, on pages 4 and 6 of the Office Action, the Examiner concedes that Latson fails to disclose that the first deformable member has a spherical shape when expanded and that the second expansible member has a cylindrical shape when expanded. The Examiner argues, however, that such deficiencies are cured by the Khairkhahan '647 publication, relying on Fig. 10 to teach a spherical shape when expanded. Such reliance is misplaced.

While Fig. 10 of Khairkhahan does show a generally spherical occlusion member, this occlusion member is not intended to be combined with a second occlusion or expansible member, and one skilled in the art would hardly look to such a unitary or integrated device to modify the structure of the Latson '003 ASD closure device.

The Khairkhahan '647 publication teaches a device intended for closing a left atrial appendage. A first embodiment of the device, as generally illustrated in Figs. 1-6, includes a bulking element or stabilizer 194 in tandem with the barrier 15. The bulking element/stabilizer is intended to anchor within the enclosed distal end of the left atrial appendage while the barrier blocks the opening into the atrium. The device as illustrated in Figs. 1-6 is not intended to be positioned across an ASD, as is the intent of the Latson '003 device.

While the embodiment of Figs. 1-6 of Khairkhahan '647 is structurally analogous to the ASD closure device of Latson '003 in that both include two expansible members in tandem, the Khairkhahan device never teaches that either of the elements is spherical or cylindrical.

A second embodiment of Khairkhahan, as shown in Fig. 10 relied on by the Examiner, does describe a generally spherical occlusion element. That occlusion element, however, is not intended to be connected to any other expansible element and would not be suitable for placement across an ASD as is the purpose of the Latson '003 device. Instead, the Khairkhahan device of Fig. 10 is intended to occupy an entire opening to the left atrial appendage and to be held in place by barbs 195.

The Examiner argues that it would have been obvious “to use the shape of Khairkhahan with the device of Latson as the spherical shape may be preferable in different applications, as the front face would be rounded instead of flat, making the entry of the device into a certain body part smoother. The sphere of Khairkhahan is structurally stronger than the disk of Latson, because the stress concentration is evenly distributed in a sphere.”

The Examiner, in making the above assertion, ignores the entirely different purposes of the Latson device and the Khairkhahan device. Latson is intended to seal an atrial septal defect between the atria of a heart, where the proximal sac 5 and distal sac 6 are necessarily disk-shaped so they do not significantly intrude into the atrium. In contrast, the Khairkhahan ‘647 device is intended to occupy and occlude a left atrial appendage. Thus, a spherical or other space-occupying geometry might be preferable, as taught, for example, in Fig. 10. One skilled in the art, however, would not look to the large volume device of Khairkhahan to substitute for the low profile components of Latson.

Indeed, substitution of the large volume device of Khairkhahan for the low profile components of Latson would be contrary to the intent and operability of the Latson device. As the Examiner is undoubtedly aware, a proposed modification to a prior art teaching cannot render the prior art unsatisfactory for its intended purpose. *See*, MPEP § 2141.03(v). In the present case, modification of the flat disk geometry of either sac 5 or 6 to assume the spherical geometry of occlusion element 15 of Khairkhahan would not provide for a component intruding into the atrium of the heart, rendering the ASD closure device of Latson unsatisfactory for its intended purpose.

Nor do either Latson or Khairkhahan disclose an expansible member having a cylindrical shape. While the Examiner, on page 4, concedes that Latson does not teach such a cylindrical shape, on page 6 the Examiner does assert that Latson teaches the second expansible member is a cylinder. Perhaps the Examiner is referring to Fig. 4, where the sac 5 is shown in an axially extended configuration. While this configuration is still not cylindrical, it is certainly not expanded as required by the claims. Applicants cannot find any teaching or suggestion in either Latson or Khairkhahan of the combination of a spherical expansible device and a cylindrical expansible device, where these geometries are achieved when the devices are fully expanded.

Independent claims 19 and 29, as well as several claims dependent thereon, were also rejected as being unpatentable over the combination of Latson and Khairkhahan, as applied to claim 29 discussed above, further in view of Brenneman '300. The Examiner observes that neither Latson nor Khairkhahan teach the specified locations of the first and second expansible members and asserts that Brenneman "teaches the first expansible member is deployed against a blood vessel wall (fig. 1.) and the second expansible member is deployed against a tissue tract (fig. 1)."

As an initial matter, Applicants do not understand how claim 29 could have been rejected over the combination of Latson and Khairkhahan if this element is missing. Nonetheless, Applicants will respond to this further, alternative rejection by pointing out that Brenneman does not cure the fundamental failure of both Latson and Khairkhahan to teach the spherical and cylindrical expansible members. Without this teaching, the Examiner has failed to establish *prima facie* obviousness, either with or without the Brenneman patent.

For these reasons, Applicants believe that all pending claims, even prior to amendment, clearly distinguish the teachings of Latson and Khairkhahan. Nonetheless, in order to expedite prosecution and as suggested by the Examiner, Applicants have amended independent claims 19 and 29 to more specifically recite that the second expansible member comprises an elongate cylinder having a length sufficient to extend through at least a portion of the tissue tract from the blood vessel to the skin surface. Neither Latson nor Khairkhahan teach a device having an occlusive element which would be capable of assuming an elongated cylindrical configuration nor which would be capable of extending through at least a portion of the tissue tract from the blood vessel to the skin surface. For these reasons, Applicants believe that all claims herein are now in condition for allowance.

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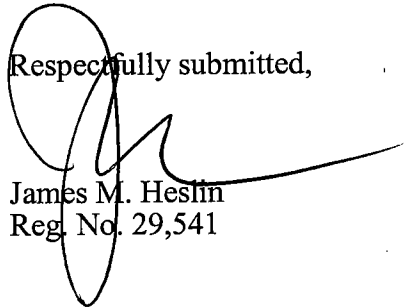
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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